UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHIESI USA, INC. and CHIESI FARMACEUTICI S.P.A., Plaintiffs, v. AUROBINDO PHARMA USA, INC. and AUROBINDO PHARMA LTD., Defendants.	Civil Action No. 3:19-cv-18756-ZNQ-LHG

FINAL JUDGMENT ORDER

This action, having come to trial before the Court, Honorable Zahid N. Quraishi, District Judge presiding, the issues having been heard and a decision having been rendered:

IT IS HEREBY ORDERED AND ADJUDGED this 30th day of August, 2022, for the reasons set forth in the Court's Memorandum Opinion dated August 16, 2022 (ECF No. 388) ("Opinion") that:

1. Judgment is entered in favor of Plaintiffs Chiesi USA, Inc. and Chiesi Farmaceutici S.p.A. (together, "Chiesi" or "Plaintiffs") and against Defendants Aurobindo Pharma USA, Inc., Aurobindo Pharma Ltd., and Eugia Pharma Specialities Limited (collectively, "Aurobindo" or "Defendants") on all of Plaintiffs' claims (ECF No. 148, Counts I-III) and Aurobindo's counterclaims (ECF No. 149, Counts I-VIII), with respect to claims 1 and 8 of U.S. Patent No. 8,658,676 (the "'676 patent"), claim 7 of U.S. Patent No. 10,010,537 (the "'537 Patent"), and claim 6 of U.S. Patent No. 11,103,490 (the "'490 patent"). Claims 1 and 8 of the '676 patent, claim 7 of the '537 patent, and claim 6 of the '490 patent are infringed, not invalid, and not unenforceable.

2. By submitting Abbreviated New Drug Application ("ANDA") No. 213280 seeking approval to market clevidipine injectable emulsion, 25 mg/50ml (0.5 mg/ml) and 50 mg/100ml (0.5 mg/ml) single-dose vials ("Aurobindo's ANDA Product"), Aurobindo has infringed claims 1 and 8 of the '676 patent, claim 7 of the '537 patent, and claim 6 of the '490 patent.

3. If Aurobindo commercially manufactures, uses, markets, offers to sell, or sells Aurobindo's ANDA Product within the United States, or imports Aurobindo's ANDA Product into the United States, Aurobindo will infringe claims 1 and 8 of the '676 patent, claim 7 of the '537 patent, and claim 6 of the '490 patent.

4. For as long as claims 1 and 8 of the '676 patent, claim 7 of the '537 patent, and claim 6 of the '490 patent remain extant and enforceable, pursuant to 35 U.S.C. § 271(e)(4)(A), the Food and Drug Administration ("FDA") cannot finally approve ANDA No. 213280 earlier than the latest date of expiration of the '676, '537 and '490 patents (October 10, 2031), including any periods of regulatory exclusivity associated with the '676, '537, and '490 patents authorized by the FDA, such as pediatric exclusivity under 21 U.S.C. § 355a.

5. For as long as claims 1 and 8 of the '676 patent, claim 7 of the '537 patent, and claim 6 of the '490 patent remain extant and enforceable, pursuant to 35 U.S.C. § 271(e)(4)(B), Aurobindo and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them, as well as any successors and/or assignees of ANDA No. 213280, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the proposed clevidipine product described in ANDA No. 213280 until the latest expiration of the '676, '537 and '490 patents except to the extent subsequently (a) agreed between the Parties or (b) ordered or otherwise permitted by this

Court or other tribunal with proper authority. If Plaintiffs become entitled to new regulatory exclusivities, such as pediatric exclusivity under 21 U.S.C. § 355a, Plaintiffs may apply to the Court for further relief as may be appropriate. This injunction order is effective as of the Court's August 16, 2022 Opinion.

6. Pursuant to Rule 54(d) of the Federal Rules of Civil Procedure and 28 U.S.C. 1920, Plaintiffs are the prevailing parties and shall recover their costs from Defendants.

7. Any other outstanding requests for relief not specifically addressed herein are DENIED. This is a final, appealable, judgment.

8. The Clerk's Office is instructed to mark this matter CLOSED.

Entered: August 30, 2022

s/ Zahid N. Quraishi

Hon. Zahid N. Quraishi, U.S.D.J.